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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,544	10/17/2001	Ira G. Schulman	509132000100	7779

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/982,544	SCHULMAN ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *06 May 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *13,16,21-23,30,34 and 36*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *See Continuation Sheet*

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejection of claims 17 and 31 under 35 U.S.C. 112, first paragraph .

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, first paragraph for claims 13,16, 21-23, 30, 34 and 36 .

Continuation of 10. Other: The amendment to the claims does not resolve the current issues under 35 USC 112, first paragraph. In the amendment of May 6, 2004, claims 16 and 23 have been amended, and claims 17 and 31 have been cancelled. Applicants' response has been fully considered, however, claims 13, 16, 21-23, 30, 34 and 36 are rejected under 35 USC 112, first paragraph.

Claims 13, 16, 21-23, 30, 34 and 36 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a method of treating diabetes or type II diabetes, the method comprising administering an amount of a specific LXR agonist, compound 1 effective to decrease hyperglycemia or to decrease insulin resistance, does not reasonably provide enablement for a method for treating diabetes or type II diabetes, the method comprising administering an LXR agonist effective to decrease hyperglycemia or to decrease insulin resistance, wherein the structure of the LXR agonist is not defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims because the specification only indicates compound 1 can reduce hyperglycemia (elevated blood glucose) in the diabetic mice (pages 38-39, paragraphs 0121-0122, Fig. 15), however, it does not demonstrate the effects of various LXR agonists in the treatment of diabetes or type II diabetes, as encompassed by the claims. Moreover, the specification has not shown the treating conditions such as dosage of various LXR agonists, nor has demonstrated the effects of various LXR agonists in the treatment. There are no working examples indicating the claimed methods using various LXR agonists having different structures. Since the specification fails to provide sufficient teachings on the use and effects of various LXR agonists, it is necessary to have additional guidance regarding the structure/function relationship and to carry out further experimentation to assess the effects of various LXR agonists in the treatment.
In response, applicants indicate the current pending claims are fully enabled by the specification and the knowledge of the skilled practioner; the fact that LXR agonists have been defined in the past in relation to lipid metabolism does not negate or alter the discovery that the agonists may be effectively used to decrease hyperglycemia and insulin resistance; the invention is directed to the use of LXR agonists in the method of treating diabetes, since various structures of LXR agonists are known, and the method is based on the function of LXR agonist rather than any particular compound structure; a copy of Cao et al., (J. Biol. Chem. 278, 1131-1136 (2203), a post filing date reference is provided to support applicants' position that LXR agonists can be used to decrease hyperglycemia, thus to treat dibetes and insulin resistance, and the reference provides a possible mechanism by which LXR agonists act; and regarding the need to define dosages for additional LXR agonists, undue experimentation is not the absence of experiemntation, the routine and repetitive experimentation is not undue for the determination of dosage for various LXR agonists, which is supported by Cao, et al. (pages 5-8 of the response). The response has been fully considered, however, the argument is not found persuasive because the specification only describes using a specific LXR agonist (compound 1, a sulfonamide) to treat diabetes, it does not disclose the treating conditions such as the doses for other LXR agonists containing different structures (e.g., oxysterol derivatives and TOFA) in the treatment of diabetes, since they have different structures, the doses and effects of these various LXR agonists in treating diabetes requires further experimentation, which are undue since the proper dosage of agonists requires further research. Moreover, the claimed method encompasses the use of unspecified LXR agonists, where the correlation of structures and activities of the LXR agonists are not described in the specification, thus their effects in the treating diabetes are not known. Regarding the reference provded by applicant, Cao et al. teach T0901317 reduces plasma glucose levels and improves insulin sensitivity in insulin resistance rats, which supports the claimed invention with a specific LXR agonist, compound 1, since T0901317 has the same structure as compound 1 (see page 30,paragraph 0105, the chemical name of compound 1, and structure of T0901317 indicated in WO 0103705, Fig. 9). Thus, as indicated in the section above, the full scope of the claims is not enabled by the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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May 24, 2004

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